

House File 233

H-1239

1 Amend the amendment, H-1235, to House File 233, as follows:

2 1. Page 1, by striking lines 2 through 26 and inserting:

3 <___. By striking everything after the enacting clause and
4 inserting:

5 Section 1. NEW SECTION. 514F.7 Use of step therapy
6 protocols.

7 1. *Definitions.* For the purposes of this section:

8 a. "*Authorized representative*" means the same as defined in
9 section 514J.102.

10 b. "*Clinical practice guidelines*" means a systematically
11 developed statement to assist health care professionals and
12 covered persons in making decisions about appropriate health
13 care for specific clinical circumstances and conditions.

14 c. "*Clinical review criteria*" means the same as defined in
15 section 514J.102.

16 d. "*Covered person*" means the same as defined in section
17 514J.102.

18 e. "*Health benefit plan*" means the same as defined in
19 section 514J.102.

20 f. "*Health care professional*" means the same as defined in
21 section 514J.102.

22 g. "*Health care services*" means the same as defined in
23 section 514J.102.

24 h. "*Health carrier*" means an entity subject to the
25 insurance laws and regulations of this state, or subject
26 to the jurisdiction of the commissioner, including an
27 insurance company offering sickness and accident plans, a
28 health maintenance organization, a nonprofit health service
29 corporation, a plan established pursuant to chapter 509A
30 for public employees, or any other entity providing a plan
31 of health insurance, health care benefits, or health care
32 services. "*Health carrier*" includes an organized delivery
33 system. "*Health carrier*" does not include a managed care
34 organization as defined in 441 IAC 73.1 when the managed care
35 organization is acting pursuant to a contract with the Iowa

1 department of human services to provide services to Medicaid
2 recipients.

3 *i. "Pharmaceutical sample"* means a unit of a prescription
4 drug that is not intended to be sold and is intended to promote
5 the sale of the drug.

6 *j. "Step therapy override exception"* means a step therapy
7 protocol should be overridden in favor of coverage of the
8 prescription drug selected by a health care professional
9 within the applicable time frames and in compliance with the
10 requirements specified in section 505.26, subsection 7, for a
11 request for prior authorization of prescription drug benefits.
12 This determination is based on a review of the covered person's
13 or health care professional's request for an override, along
14 with supporting rationale and documentation.

15 *k. "Step therapy protocol"* means a protocol or program that
16 establishes a specific sequence in which prescription drugs for
17 a specified medical condition and medically appropriate for
18 a particular covered person are covered under a pharmacy or
19 medical benefit by a health carrier, a health benefit plan, or
20 a utilization review organization, including self-administered
21 drugs and drugs administered by a health care professional.

22 *l. "Utilization review"* means a program or process by which
23 an evaluation is made of the necessity, appropriateness, and
24 efficiency of the use of health care services, procedures, or
25 facilities given or proposed to be given to an individual.
26 Such evaluation does not apply to requests by an individual or
27 provider for a clarification, guarantee, or statement of an
28 individual's health insurance coverage or benefits provided
29 under a health benefit plan, nor to claims adjudication.
30 Unless it is specifically stated, verification of benefits,
31 preauthorization, or a prospective or concurrent utilization
32 review program or process shall not be construed as a guarantee
33 or statement of insurance coverage or benefits for any
34 individual under a health benefit plan.

35 *m. "Utilization review organization"* means an entity that

1 performs utilization review, other than a health carrier
2 performing utilization review for its own health benefit plans.

3 2. *Establishment of step therapy protocols.* A health
4 carrier, health benefit plan, or utilization review
5 organization shall consider available recognized evidence-based
6 and peer-reviewed clinical practice guidelines when
7 establishing a step therapy protocol. Upon written request
8 of a covered person, a health carrier, health benefit plan,
9 or utilization review organization shall provide any clinical
10 review criteria applicable to a specific prescription drug
11 covered by the health carrier, health benefit plan, or
12 utilization review organization.

13 3. *Step therapy override exceptions process transparency.*

14 a. When coverage of a prescription drug for the
15 treatment of any medical condition is restricted for use
16 by a health carrier, health benefit plan, or utilization
17 review organization through the use of a step therapy
18 protocol, the covered person and the prescribing health
19 care professional shall have access to a clear, readily
20 accessible, and convenient process to request a step therapy
21 override exception. A health carrier, health benefit plan, or
22 utilization review organization may use its existing medical
23 exceptions process to satisfy this requirement. The process
24 used shall be easily accessible on the internet site of the
25 health carrier, health benefit plan, or utilization review
26 organization.

27 b. A step therapy override exception shall be approved by
28 a health carrier, health benefit plan, or utilization review
29 organization if any of the following circumstances apply:

30 (1) The prescription drug required under the step therapy
31 protocol is contraindicated pursuant to the drug manufacturer's
32 prescribing information for the drug or, due to a documented
33 adverse event with a previous use or a documented medical
34 condition, including a comorbid condition, is likely to do any
35 of the following:

1 (a) Cause an adverse reaction to a covered person.
2 (b) Decrease the ability of a covered person to achieve
3 or maintain reasonable functional ability in performing daily
4 activities.
5 (c) Cause physical or mental harm to a covered person.
6 (2) The prescription drug required under the step therapy
7 protocol is expected to be ineffective based on the known
8 clinical characteristics of the covered person, such as the
9 covered person's adherence to or compliance with the covered
10 person's individual plan of care, and any of the following:
11 (a) The known characteristics of the prescription drug
12 regimen as described in peer-reviewed literature or in the
13 manufacturer's prescribing information for the drug.
14 (b) The health care professional's medical judgment based
15 on clinical practice guidelines or peer-reviewed journals.
16 (c) The covered person's documented experience with the
17 prescription drug regimen.
18 (3) The covered person has had a trial of a therapeutically
19 equivalent dose of the prescription drug under the step
20 therapy protocol while under the covered person's current or
21 previous health benefit plan for a period of time to allow for
22 a positive treatment outcome or of another prescription drug
23 in the same pharmacologic class or with the same mechanism
24 of action, and such prescription drug was discontinued by
25 the covered person's health care professional due to lack of
26 effectiveness.
27 (4) The covered person is currently receiving a positive
28 therapeutic outcome on a prescription drug selected by the
29 covered person's health care professional for the medical
30 condition under consideration while under the covered person's
31 current or previous health benefit plan. This subparagraph
32 shall not be construed to encourage the use of a pharmaceutical
33 sample for the sole purpose of meeting the requirements for a
34 step therapy override exception.
35 c. Upon approval of a step therapy override exception, the

1 health carrier, health benefit plan, or utilization review
2 organization shall authorize coverage for the prescription
3 drug selected by the covered person's prescribing health care
4 professional if the prescription drug is a covered prescription
5 drug under the covered person's health benefit plan.

6 *d.* A health carrier, health benefit plan, or utilization
7 review organization shall make a determination to approve or
8 deny a request for a step therapy override exception within the
9 applicable time frames and in compliance with the requirements
10 specified in section 505.26, subsection 7, for a request for
11 prior authorization of prescription drug benefits.

12 *e.* If a request for a step therapy override exception is
13 denied, the health carrier, health benefit plan, or utilization
14 review organization shall provide the covered person or the
15 covered person's authorized representative and the patient's
16 prescribing health care professional with the reason for the
17 denial and information regarding the procedure to request
18 external review of the denial pursuant to chapter 514J. Any
19 denial of a request for a step therapy override exception
20 that is upheld on appeal shall be considered a final adverse
21 determination for purposes of chapter 514J and is eligible
22 for a request for external review by a covered person or the
23 covered person's authorized representative pursuant to chapter
24 514J.

25 *4. Limitations.* This section shall not be construed to do
26 either of the following:

27 *a.* Prevent a health carrier, health benefit plan, or
28 utilization review organization from requiring a covered
29 person to try a prescription drug with the same generic name
30 and demonstrated bioavailability or a biological product that
31 is an interchangeable biological product pursuant to section
32 155A.32 prior to providing coverage for the equivalent branded
33 prescription drug.

34 *b.* Prevent a health care professional from prescribing
35 a prescription drug that is determined to be medically

1 appropriate.

2 Sec. 2. APPLICABILITY. This Act is applicable to a health
3 benefit plan that is delivered, issued for delivery, continued,
4 or renewed in this state on or after January 1, 2018.>

5 2. By renumbering as necessary.

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